

REMARKSApplication Status and Disposition of Claims

This amendment responds to the non-final Office Action mailed February 17, 2011. Inasmuch as the Office Action sets a three-month shortened statutory period for response to expire on May 17, 2011, Applicants respectfully submit that this response is timely filed and no fee is required for its consideration.

The Action considered all pending claims: 1-8, 14, and 19-21.

By the foregoing amendments, claim 1 is amended. This amendment finds support throughout the specification. In particular, Fig. 9 shows pellets 1A-1D in cross-section having a solid construction and being without any through openings. Also, Fig. 1 shows an exemplary pellet having a surface adjoining to the pair of opposite, non-parallel surfaces as well as that the other of the opposite, non-parallel surfaces is perpendicular to the surface adjoining to the pair of opposite, non-parallel surfaces.

Obviousness-Type Double Patenting

The Action rejects claims 1-8, 14, and 19-21 for obviousness-type double patenting over claims 1-15 of U.S. Patent No. 7,238,209 in view of Kim et al. (U.S. Patent No. 5,645,596) and in further view of Tofight et al. (U.S. Published Application No. 2003/0120351 which was incorrectly listed in the Office Action as No. 2003/0052829).

In response, Applicants submit herewith an executed Terminal Disclaimer. Applicants respectfully request withdrawal of the rejection.

Applicants note that the concurrently filed Terminal Disclaimer addresses the alleged deficiencies of the previously filed "not accepted" Terminal Disclaimer.

Claim Rejection – 35 U.S.C. § 112

The Action rejects claims 1-8, 14, and 19-21 under 35 U.S.C. § 112, 2nd paragraph, as allegedly indefinite.

In regards to the element “each pellet” in claim 1 being indefinite, Applicants notes that this element has been replaced with “the pellet”. As such, this basis of rejection is believed to be overcome and should be withdrawn.

Claim Rejections – 35 U.S.C. § 103

The Action rejects claims 1-8, 14, and 19-21 under 35 U.S.C. § 103(a) as allegedly unpatentable over Stone et al. (U.S. Patent No. 6,387,130) in view of Shimp (U.S. Published Application No. 2004/0052829) in further view of Kim et al. (U.S. Patent No. 5,645,596) and in further view of Tofighi et al. (U.S. Published Application No. 2003/0120351). Applicants respectfully submit that the combination of references fails to create a *prima facie* case of obviousness for the reasons that follow.

With respect to Stone et al., the Action asserts that while Stone lacks a number of feature recited in claim 1, Stone teaches a pellet 20 which is shown in Figs. 4 and 5 as having the recited shape and surfaces and which is capable of being of being used in the claimed manner.

Applicants respectfully disagree that Stone teaches the recited shape and surfaces and that is capable of being of being used in the claimed manner, as now recited in claim 1. Applicants direct the Examiner’s attention to Fig. 7 of Stone reproduced below.

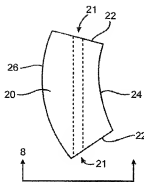


FIG. 7

Applicants respectfully submit that the present claims require a number of features which are not disclosed, or even suggested, by the pellet shown in Fig. 7 of Stone.

Claim 1 as herein amended recites the other of the opposite, non-parallel surfaces is perpendicular to the surface adjoining to the pair of opposite, non-parallel surfaces. Although Fig. 8 of Stone shows two surfaces which adjoin the opposite surfaces 22, it is not apparent that any of these surfaces 22 are properly characterized as being perpendicular to the surface adjoining to the pair of opposite, non-parallel surfaces.

Claim 1 as herein amended also recites that the pellet is formed free of a through hole being provided therethrough. Applicants respectfully submit that at least this feature of the claims excludes the embodiments of Stone. In Stone, each embodiment shown in the drawings includes at least one through opening (see col. 3, lines 49-51). Indeed, col. 3, lines 51-55 of Stone explains how this opening is provided in order to facilitate installation using an elongated member as follows:

An elongated member 30 is threaded through holes 21 on each of intervertebral implants 20A, 20B, and 20C such that implants 20A, 20B, and 20C can be sequentially advanced thereover, as will be explained.

This distinction is not without a difference. First, Applicants' invention does not require a through opening in the pellet because it does not utilize an elongated member which passes therethrough. Instead, packing of the bone replacement material pellet into a cavity of the bone

defective part can be accomplished using a cylindrical member having a hollow passage. This is clearly shown in Applicants' Fig. 9, which is reproduced below:

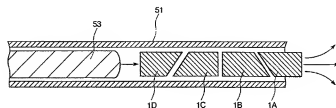


FIG 9

As is apparent from the above-noted Fig. 9, the pellets can be moved or pushed through the cylindrical member 51 without requiring any elongated member passing through the pellets. As such, no through openings in the pellets is required.

A second distinction is evident when one compares the above-noted Fig. 9 with Figs. 4A and 4B of Stone. Whereas the shape of the pellets allows the pellets in the cylindrical member to be inserted with essentially go gaps between the pellets, this cannot occur in the configuration shown in Fig. 4A of Stone. A configuration which removes the gaps as shown in Fig. 4B would prevent the pellets from being arranged in a cylindrical member of the type shown in Applicants Fig. 9. At the very least, it would require a significant enlarging of the cannula to accommodate the configuration of Fig. 4B. As this would make it more difficult to perform low-invasive surgery, such a modification would be contrary to the express teachings of Stone (see col. 1, lines 36-42 and col. 2, lines 10-11 and 17-20).

A third distinction relates to the fact that Stone specifically desires that the implant exhibit a "C-shaped" configuration (see col. 2, lines 5-9). This would not occur in a cylindrical member that has a "narrow opening" (see col. 2, line 11 of Stone) if the pellets of Stone utilized substantially no gaps.

A fourth distinction relates to the fact that configuration of Fig. 4B necessarily results in fewer pellets being introduced each time. When one compares the tighter packing configuration of Fig. 9 of the instant application (as a result of essentially go gaps between the pellets) to that shown in Figs. 4A and 3 of Stone (which utilizes large gaps between the pellets) one can see how

the invention has the advantage of reducing the number of times required to introduce sufficient pellets into a cavity of the defective part. Indeed, in Fig. 3 of Stone reproduced below, the gaps between the pellets are large indeed as they appear to be almost 50% of the length of the pellets:

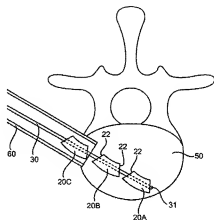


FIG. 3

A fifth distinction relates to the recited collapsing strength is equal to or more than 15Mpa. While the Examiner has correctly acknowledged that this feature is lacking in Stone (see last sentence on page 6 of the instant Office Action), the Examiner did not appear to appreciate that the through opening in the pellets of Stone may necessarily prevent the disclosed pellets from meeting this limitation, even if made of the material(s) disclosed in any of the secondary references. Indeed, because the pellets of Stone have a through opening and utilize large gaps between the pellets, they would not appear to require any particular collapsing strength. The gaps, for example, would appear to negate the need for the pellets to have any significant collapsing strength along the length direction. Moreover, the fact that Stone places an elongated member in the opening of the pellets would serve to reinforce the pellets along the width or thickness direction, thereby undercutting the need or concern for the pellets having any particular collapsing strength.

Applicants submit that the secondary references cited in the rejection fail to cure the numerous noted deficiencies of Stone for the following reasons.

In regards to Shimp, it is noted that while Ship teaches a composition for repairing bones (see Abstract), this document contains no disclosure whatsoever with regard to forming pellets having any one of the recited features related to shape, surfaces, edges, porosity and collapsing strength. Moreover, the disclosed “flowable” composition is not analogous (and indeed appears contrary) to pellets having a predetermined collapsing strength. A flowable composition is more analogous to a fluid which typically has little compressive strength and is compressible only when confined in a defined volume. When one considers that Stone teaches away from making pellets without through openings (thereby undermining the need for a predetermined collapsing strength) and that Shimp teaches away from making pellets with a predetermined collapsing strength by utilizing a flowable composition, combining the teachings of Stone and Shimp appears problematic.

In regards to Kim, it is noted that while Kim teaches a ceramic prosthesis (see Abstract), this document contains no disclosure whatsoever with regard to forming pellets having any one of the recited features related to shape, surfaces, edges, porosity and collapsing strength. Moreover, such a prosthesis is not analogous to pellets, is not configured to pass through a cylindrical member, and is not a bone repair material. Nor is the cement disclosed in Kim used to secure the prosthesis properly characterized as a pellet. Such a material is typically designed to conform to irregular surfaces and would not exhibit a predetermined collapsing strength. When one considers that Kim says nothing about making or introducing pellets (thereby undermining the need for a predetermined collapsing strength) and that each of Stone and Shimp teaches away from making pellets with a predetermined collapsing strength as noted above, combining the teachings of Stone, Shimp and Kim appears even problematic.

In regards to Tofighi, it is noted that while Tofighi teaches a calcium phosphate powder for bone substitute materials (see paragraph [0003]), this document contains no disclosure whatsoever with regard to forming pellets having any one of the recited features related to shape, surfaces, edges, porosity and collapsing strength. Indeed, Tofighi refers only to a “cement” material (see paragraph [0013]) and not to pellets configured to pass through a cylindrical member. When one considers that Tofighi says nothing about making or introducing pellets having the recited features, and that each of Stone, Shimp, Kim and Tofighi teaches away from

making pellets with a predetermined collapsing strength, combining the teachings of Stone, Shimp, Kim and Tofighi appears entirely without any rational basis in the art.

Thus it is submitted that the above-noted rejection is improper and should be withdrawn.

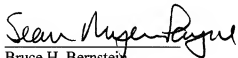
Conclusion

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
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Attachments: Executed Terminal Disclaimer

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